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Can nurse delivered cognitive behavioural therapy reduce the impact of hot flushes and night sweats in women who have had breast cancer?

Submission date 04/01/2017	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 25/01/2017	**Overall study status** Completed	
Last Edited 15/09/2022	**Condition category** Cancer	

Plain English summary of protocol
http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-cognitive-behavioural-therapy-to-reduce-the-impact-of-hot-flushes-and-night

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
33060

Study information

Scientific Title
A multicentre randomised controlled trial of a breast care nurse delivered cognitive behavioural therapy (CBT) intervention to reduce the impact of hot flushes in women with breast cancer

Acronym
MENOS 4

Study objectives
The aim of this study is to evaluate whether group cognitive behavioural therapy (CBT) delivered by NHS breast care nurses can effectively reduce the impact of hot flushes in women who have completed treatment for breast cancer.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South Central – Hampshire A Research Ethics Committee, 17/08/2016, ref: 16/SC/0364

Study design
Randomised; Interventional; Design type: Treatment, Psychological & Behavioural, Complex Intervention

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Specialty: Cancer, Primary sub-specialty: Breast Cancer; UKCRC code/ Disease: Cancer/ Malignant neoplasm of breast

Interventions
Randomised Controlled Trial:
Women will be randomly allocated 1:1 to one of two groups.

Investigative treatment (Group CBT) only:
Patients allocated to receive group CBT treatment will be invited to attend six therapy sessions, one per week, at or near their local hospital. Sessions will be led by a trained breast care nurse, following a structured manual, and will last 90 minutes each. These sessions will be recorded to check the quality of the session delivered. Some participants will also be asked to take part in face-to-face interviews to ask some more questions about how they felt about the therapy and get feedback about things not covered by the questionnaires. Approximately 1-2 people from each group will be invited to take part in these interviews.

Standard care only:
Patients allocated to receive standard care. They will not be invited to group therapy sessions but at the end of the study, will be offered a booklet and CD that includes the same information delivered through group CBT sessions. A one-to-one meeting with a breast care nurse to discuss the main parts of the booklet may be arranged, followed by two follow up telephone calls to discuss progress and address any problems.

Participants in both groups will be sent a questionnaire booklet to complete at weeks 9 and 26. Some participants who receive the group CBT intervention will also be invited to take part in optional interviews.

Process Evaluation:
A group evaluation questionnaire will be administered at the end of the six-week intervention to those participants in the intervention arm. Interviews will be conducted with patients and key stakeholders from each of the study centres at the completion of the intervention. Semi structured interview schedules will be developed, guided by consideration of the four areas identified through Normalisation Process Theory. An experienced clinical psychologist, who is independent of the study team, will rate a random selection of group session recordings and rate them for adherence to the treatment manual.

Intervention Type
Other

Phase
Phase III

Primary outcome measure
Randomised Controlled Trial:
Impact of hot flushes and night sweats is measured using the Hot Flush and Night Sweats (HFNS) Problem Rating (1–10) at baseline and 26 weeks

Process Evaluation:
Acceptability of intervention is assessed through participant interviews, fidelity ratings of recordings of the intervention, an unvalidated questionnaire and session attendance figures at study end.

Secondary outcome measures

1. Impact of hot flushes and night sweats is measured using the Hot Flush and Night Sweats (HFNS) Problem Rating (1–10) at baseline and 9 weeks
2. Sleep quality is measured using the Pittsburgh Sleep Quality Index at baseline, 9 and 26 weeks
3. Impact of hot flushes on daily activities and overall quality of life is measured using the Hot flash related daily interference scale at baseline, 9 and 26 weeks
4. Anxiety is measured using the Generalised Anxiety Disorder Questionnaire at baseline, 9 and 26 weeks
5. Depression is measured using the Patient Health Questionnaire at baseline, 9 and 26 weeks
6. Health-related quality of life is measured using the FACT B + ES at baseline,9 and 26 weeks
7. Hot flush beliefs and behaviours is measured using the Hot Flush Beliefs and Behaviour Scale (Short Form) at baseline, 9 and 26 weeks
8. Quality of life is measured using the EQ-5D-5L at baseline, 3, 6, 9 and 26 weeks

Overall study start date
04/01/2016

Completion date
03/01/2019

Eligibility

Key inclusion criteria
Randomised controlled trial:
1. Women with primary breast cancer or DCIS
2. Women who have completed primary surgery radiotherapy and chemotherapy (may still be receiving adjuvant endocrine therapy or Herceptin)
3. Aged 16 years and over
4. Experiencing seven or more problematic HFNS/week, with an overall problem rating score of 4 /10 or more
5. Ability and willingness to attend group sessions
6. Written informed consent

Process evaluation:
1. BCNs delivering the intervention (2 from each centre)
2. Purposively selected participants from the intervention arm who have consented to be interviewed (2 from each centre)
3. Managers and medical staff from participating centres, who are responsible for breast care services (1 manager and 1 member of the medical team from each centre)

Participant type(s)
Patient

Age group
Adult

Lower age limit
16 Years

Sex
Female

Target number of participants
Planned Sample Size: 160; UK Sample Size: 160

Total final enrolment
130

Key exclusion criteria
Randomised controlled trial:
1. Benign breast disease
2. Metastatic disease
3. Current use of other therapies to help with HFNS, e.g. acupuncture, hypnosis and mindfulness

Process evaluation:
Participants who have not indicated that they are happy to be interviewed on the Consent Form.

Date of first enrolment
01/02/2017

Date of final enrolment
01/03/2018

Locations

Countries of recruitment
England

United Kingdom

Wales

Study participating centre
Walsall Manor Hospital
Moat Road
Walsall
United Kingdom
WS2 9PS

Study participating centre
York Hospital
Wigginton Road
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YO31 8HE

Study participating centre
Yeovil District Hospital
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Study participating centre
Luton and Dunstable University Hospital
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Study participating centre
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Sponsor type
University/education

ROR
https://ror.org/01ryk1543

Funder(s)

Funder type
Charity

Funder Name
Breast Cancer Now

Alternative Name(s)
BCN

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal around 6 months after trial end.

Intention to publish date
03/07/2019

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	08/05/2018		Yes	No
Results article		01/10/2020	20/05/2021	Yes	No
Plain English results			15/09/2022	No	Yes
HRA research summary			28/06/2023	No	No